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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,615	04/20/2007	Yuzuru Umeda	1691-0217PUS1	4241
2292 7590 02/06/2009 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			EXAMINER BASQUILL, SEAN M	
			ART UNIT	PAPER NUMBER
			1612	
			NOTIFICATION DATE	DELIVERY MODE
			02/06/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/574,615	Applicant(s) UMEDA ET AL.	
	Examiner Sean Basquill	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicants are advised, in future correspondence with the office, to reflect the change of examiners from SRIRAM KASTURI to SEAN BASQUILL.

Previous Rejections

1. Applicants' arguments, filed 27 October 2008, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of Claims

2. The Claim amendments filed 27 October 2008 have been entered, resulting in the cancellation of Claims 13 and 14. Claims 1-12 are presented for examination.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1-12 stand rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,116,868 ("Chen") as put forth in the previous action.

The current examiner would like to clarify a few matters of claim interpretation. The examiner notes that the clause "and is used to treat tear abnormality," and language dependent from it neither requires steps to be performed, nor limits the claim to a particular structure.

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MPEP § 2111.04 This language simply recites an intended use of the claimed compound. This language is therefore of no significance to construction of the claims. *See* MPEP § 2111.02 (indicating preamble language reciting intended use of a claimed invention is of no significance in claim construction). Claim 1 and all dependent from it therefore recite nothing more than a composition “which comprises 3-hydroxybutyric acid and/or salts thereof as active ingredients.” Also, the examiner notes that the phrase “tear abnormality” as used in instant Claim 12 has not been clearly, deliberately, and precisely defined by the applicants in their disclosure as required to “serve as their own lexicographer.” MPEP § 2111.01(IV). The phrase “tear abnormality” will therefore be interpreted broadly, encompassing any alteration in the quantity, type, or quality of tear production including any variation from what would be considered a “normal” condition of the surface of the eye, including dry eye.

Turning to applicants’ arguments, the examiner has reviewed them and found them unpersuasive. Chen clearly discloses an ophthalmic solution comprising beta-hydroxybutyrate at 10mM concentration. Moreover, given the only component in the instantly claimed composition is 3-hydroxybutyric acid and/or salts thereof, it is the examiner's position that the composition described by Chen inherently possesses all the properties recited by instant Claims 1-9 and 12.

4. Claims 1-12 stand rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 6,495,598 (“Yoneda”) as put forth in the previous action.

The examiner reiterates his interpretation of instant Claims 1-12 as put forth above. The examiner has reviewed the applicants’ arguments and found them unpersuasive. Yoneda clearly discloses an ophthalmic solution comprising D-3-hydroxybutyric acid at 20mM concentration.

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Moreover, given the only component in the instantly claimed composition is 3-hydroxybutyric acid and/or salts thereof, it is the examiner's position that the composition described by Yoneda inherently possesses all the properties recited by instant Claims 1-9 and 12.

5. Claims 1-11 stand rejected under 35 U.S.C. 102(b) as being anticipated by Japanese Patent Application Publication JP03-313123 ("Tomoko") as put forth in the previous action.

The examiner reiterates his interpretation of instant Claims 1-11 as put forth above. The examiner has reviewed the applicants' arguments and found them unpersuasive. Tomoko clearly discloses an ophthalmic solution comprising 3-hydroxybutyric acid at a concentration of between 0.5-500mM. Moreover, given the only component in the instantly claimed composition is 3-hydroxybutyric acid and/or salts thereof, it is the examiner's position that the composition described by Tomoko inherently possesses all the properties recited by instant Claims 1-9.

Technological Background Material

The following prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Julie M. Albietz, *et al*, *Chronic Dry Eye and Regression After Laser in situ Keratomileusis for Myopia*, 30 J. CATARACT REFRACT. SURG. 675 (March 2004) discloses that ocular surgeries such as LASIK can cause sustained dysfunction of the lachrymal gland, resulting in chronic dry eye. (Pg. 675). This indicates that ocular surgery may result in tear abnormality as encompassed by the instant claims.

Conclusion

No Claims are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean Basquill whose telephone number is (571) 270-5862. The examiner can normally be reached on Monday through Thursday, between 8AM and 6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sean Basquill
Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612